REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and discussion presented herein. Claims 64-67, 70-81, and 84-92 are pending in the present application. Claims 68-69 and 82-83 have been withdrawn. Claims 93-98 have been cancelled.

1. Rejection of Claims 64-67, 70-81 and 84-92 under 35 U.S.C. § 102(b).

Claims 64-67, 70-81 and 84-92 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Swaminathan (U.S. No. 6,517,533) and Dann et al. (U.S. No. 5,899,932), hereinafter "Dann." Such rejections are traversed in part and overcome in part as follows:

a. Rejection under Swaminathan

Independent method Claim 64 recites, among other steps, inserting a catheter assembly into the general proximity of the target prostate gland, placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall, and initiating and conducting treatment of the prostate gland tissue. The above-mentioned steps are instrumental for successful treatment of the prostate gland, as the prostate is located adjacent sensitive organs such as the rectum, of which thermal treatment may be damaging. Thus, the positioning and inflation of the inflatable member between sensitive, non-target tissue (rectum) and the target prostate gland creates separation between the prostate gland and the rectum, allowing isolation of treatment to the prostate gland alone. However, the above recited elements of Claim 64 are absent from the Swaminathan reference.

Swaminathan is directed to a device and method for using cryotherapy to control or eliminate modeling or proliferation of tissue. Exemplary "clinical situations may be vascular or nonvascular applications, and may include coronary or non-coronary applications." The Swaminathan reference is void any discussion of treating the prostate gland, nonetheless placing the distal end of the inserted catheter assembly in a

space between the rectum and the prostate gland, as recited in Claim 64. Therefore, Swaminathan fails to teach or suggest all the elements of Claim 64, and thus the rejection of Claim 64 under §102 is improper.

Claims 65-67 and 70-78, being dependent from allowable base Claim 64, are therefore also allowable. However, Claims 65-67 and 70-78 also recite limitations that are not found in the cited reference. For example, Claim 72 recites, among other elements, inflating or circulating a fluid through the catheter assembly that is below the normal body temperature during the treatment of the prostate gland by thermotherapy, wherein the treatment comprises heating the prostate gland. This allows the fluid to cool surrounding tissue during thermal therapy treatment that is heating the target site. Swaminathan, in contrast, discloses a cryotherapy device that uses a liquid to cryogenically cool and treat surrounding tissue. Thus, the Swaminathan reference does not teach or suggest therapeutically heating a tissue site while circulating a liquid that is below normal body temperature.

Furthermore, Claim 73 recites the steps of inflating an inflatable member with a gas to physically displace the prostate from the rectal wall and form an acoustic barrier to protect rectal wall or surrounding tissue, and initiating and completing ultrasonic treatment of the prostate gland. As explained above, Swaminathan does not mention treatment of the prostate, particularly displacing the prostate from the rectal wall. In addition, neither of the steps of forming an acoustic barrier nor initiating ultrasonic treatment are taught or suggested by the cited art.

Currently amended independent Claim 79 recites, among other steps, placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site, inflating an inflatable member of the catheter assembly between the target tissue and non-targeted tissue to physically displace the target tissue from the non-targeted tissue, and initiating and conducting treatment of the target tissue once the inflatable member is inflated. The positioning and inflation of the inflatable member between sensitive, non-target tissue (rectum) and

the target prostate creates displacement and separation between the prostate gland and the rectum, allowing isolation of treatment to the prostate gland alone. Although Swaminathan discloses an expandable balloon, displacement of a target tissue from a non-target tissue is not taught nor suggested. Such isolation is not contemplated in Swaminathan because treatment is delivered cryogenically in all directions from the boundary of the balloon, thus isolation of tissues surrounding the Swaminathan device has no consequence.

Claims 80-81 and 84-87, being dependent from allowable base Claim 79, are therefore also allowable. However, Claims 80-81 and 84-87 also recite limitations that are not found in the cited reference. For example, Claim 84 recites, among other elements, inflating an inflatable member with a gas to physically displace the target tissue from the sensitive tissue and form an acoustic barrier, initiating and completing ultrasonic treatment of the target tissue, and replacing the gas within the inflatable member and the catheter assembly with a liquid after the conclusion of the ultrasonic treatment of the target tissue. As explained above, formation of an acoustic barrier and use of ultrasonic treatment are not taught nor suggested by Swaminathan. In addition, Swaminathan is void any discussion of use of a gas to physically displace target tissue from sensitive tissue, nor replacing the gas with a liquid.

Independent method Claim 88 recites, among other steps, placing the distal end of an inserted catheter assembly in a space between the rectum and the prostate gland, and inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall. As mentioned above with respect to Claim 64, Swaminathan is absent any discussion of treating the prostate gland, nonetheless placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland. Hence, Swaminathan fails to teach or suggest all the elements of Claim 88.

Accordingly, the rejection of Claims 64-67, 70-81, and 84-92 under § 102 in view of Swaminathan is improper, and should be removed.

b. Rejection under Dann

As mentioned above, independent method Claim 64 recites the steps of inserting a catheter assembly into the general proximity of the target prostate gland, placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, and inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall.

Dann is directed to a method of prostate treatment comprising inserting an energy emitting device into the urethra 10 and generating microwaves from an antenna 74 that is at least partially surrounded by the prostate 14 (see Abstract, Col. 6, lines 21-46, and FIGS. 5, 7). Because Dann only discloses transurethral thermal therapy (see Col. Lines 27-30), it is void any discussion of placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, as recited in claim 64. Furthermore, the device disclosed in Dann uses a retention balloon 34, which is expanded in the bladder 12 to retain the device just below the neck 11 of the bladder 12. Thus, Dann also fails to teach or suggest inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall. Therefore, Dann fails to teach or suggest all the elements of Claim 64, and the rejection of Claim 64 should be removed.

Because Claims 65-67 and 70-78 are dependent from allowable base Claim 64, their rejection is now moot. However, Claims 65-67 and 70-78 also recite limitations that are not found in the cited reference. For example, Claim 73 recites the steps of inflating an inflatable member with a gas to physically displace the prostate from the rectal wall and form an acoustic barrier to protect rectal wall or surrounding tissue, and initiating and completing ultrasonic treatment of the prostate gland. As explained above, the transurethral catheter of Dann is incapable of displacing the prostate from the rectal wall to form an acoustic barrier, as it is configured for insertion in the urethra, and the retention balloon is configured to anchor at a location away (i.e. at bladder neck 11) from the treatment site. Furthermore, Dann does not discuss ultrasonic treatment,

as it uses microwave energy to deliver therapy.

Currently amended independent Claim 79 recites, among other steps, placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site, inflating an inflatable member of the catheter assembly between the target tissue and non-targeted tissue to physically displace the target tissue from the non-targeted tissue, and initiating and conducting treatment of the target tissue once the inflatable member is inflated. As explained above, the transurethral delivery device of Dann is configured to be surrounded by target tissue (prostate 14), thus is not inserted between the target tissue site and a sensitive healthy tissue (e.g. rectum 26). Because expandable retention balloon 34 is positioned in the bladder 12 and configured to merely act as an anchor, Dann also fails to teach or suggest displacement of a target tissue from the non-targeted tissue. The Dann device is also not capable of displacing a target tissue from a non-targeted tissue, because the retention balloon 34 is located upstream (e.g. in the bladder 12) from the target tissue (prostate 14) and delivery structure (antenna 74). Accordingly, Dann fails to teach or suggest all the elements of Claim 79, and the rejection of Claim 79, and of Claims 80-81, and 84-87 dependent therefrom, is improper, and should be removed.

Independent Claim 88 similarly recites the steps of placing the distal end of an inserted catheter assembly in a space between the rectum and the prostate gland, and inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall. As explained above, Dann only discloses the transurethral placement of a delivery device and conducting treatment when the device is surrounded by the prostate gland. In addition, the expandable retention balloon 34 cited on page 3 of the present Office Action is only shown or configured to be expanded in the bladder, and thus fails to teach or suggest inflating an inflatable member between the prostate gland and the rectal wall. Because the abovementioned elements of Claim 88 have not been shown in the cited art, the rejection of Claim 88 (and dependent Claims 89-92) should be removed.

2. Amendments Made Without Prejudice or Estoppel.

Notwithstanding the amendments made and accompanying traversing remarks provided above, Applicants have made these amendments in order to expedite allowance of the currently pending subject matter. However, Applicants do not acquiesce in the original ground for rejection with respect to the original form of these claims. These amendments have been made without any prejudice, waiver, or estoppel, and without forfeiture or dedication to the public, with respect to the original subject matter of the claims as originally filed or in their form immediately preceding these amendments. Applicants reserve the right to pursue the original scope of these claims in the future, such as through continuation practice, for example.

3. Conclusion.

Based on the foregoing, Applicants respectfully request that the various grounds for rejection in the Office Action be reconsidered and withdrawn with respect to the presently amended form of the claims, and that a Notice of Allowance be issued for the present application to pass to issuance.

Date: May 7, 2007

Respectfully submitted,

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